

REMARKS

In the previous submission the original claims were generated with links and when the printing occurred the links were removed. As such, claims 16-29 lacked the dependency to claim 15. Instead the claims were linked to "0" claim. Clearly this was a mistake and not recognized by submitting attorney. However, the originally filed document, as shown in PAIR shows such dependency. Further, the published application shows the proper dependency.

In the event that any issues remain, Examiner Spivack is requested to contact the undersigned attorney at (919) 286-8089 to resolve same.

Respectfully submitted,



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disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. The terminology used in the description of the invention herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention.

[0245] All publications, patent applications, patents and other references cited herein are incorporated by reference in their entireties for the teachings relevant to the sentence and/or paragraph in which the reference is presented.

[0246] The following US patents and patent applications are incorporated herein by reference for their teaching concerning 4-APAA compounds, 5-ASA compounds and 4-APAA compounds azo bonded to 5-ASA compounds: U.S. Pat. No. 6,583,128, Immunoregulatory compounds and derivatives and methods of treating diseases therewith, filed Aug. 29, 2001; U.S. Patent Application No. 60/228,683, Immunoregulatory compounds and derivatives and methods of treating diseases therewith, filed Aug. 29, 2000, and U.S. patent application Ser. No. 10/967,736, Immunoregulatory compounds and derivatives and methods of treating diseases therewith, filed Oct. 18, 2004, and U.S. Patent Application No. 60/555,551, entitled Methods and Compositions employing 4-aminophenylacetic acid compounds, filed Mar. 23, 2004.

We claim:

1. A pharmaceutical composition comprising two or more therapeutic agents selected from the group consisting of:

- (a) azo-bonded 4-APAA compound;
- (b) non-azo bonded 4-APAA compound;
- (c) azo-bonded 5-ASA compound;
- (d) non-azo bonded 5-ASA compound;
- (e) 4-APAA compound azo bonded to a 5-ASA compound.

2. The pharmaceutical composition of claim 1 further comprising a third therapeutic agent selected from the group consisting of: steroids, antibiotics,

3. The pharmaceutical composition of claim 1 formulated to deliver the therapeutic agents to the small intestine and/or the colon.

4. The pharmaceutical composition of claim 1 formulated to release the therapeutic agents along the length of the small intestine and the colon.

5. The pharmaceutical composition of claim 1 formulated to release the therapeutic agents along the length of the distal portion of the small intestine and the colon.

6. The pharmaceutical composition of claim 1 formulated to release the therapeutic agents along the length of the colon.

7. The pharmaceutical composition of claim 1 formulated to pass through the stomach and to release the active agent in the intestine.

8. The pharmaceutical composition of claim 1 formulated as a suppository.

9. The pharmaceutical composition of claim 1 formulated for administration as an enema.

10. The pharmaceutical composition of claim 1 formulated as a mouth wash.

11. The pharmaceutical composition of claim 1 formulated for vaginal administration.

12. The pharmaceutical composition of claim 1 formulated for intrauterine administration.

13. The pharmaceutical composition of claim 1 formulated for topical administration.

14. The pharmaceutical composition of claim 1 formulated for administration to the eye.

15. The pharmaceutical composition of claim 1 formulated to release:

(a) at least one component selected from:

(i) a first component comprising one or more of the therapeutic agents formulated for release in the stomach,

(ii) a second component comprising one or more of the therapeutic agents formulated for release in the small intestine or distal portion of the small intestine, and

(b) a third component comprising one or more of the therapeutic agents formulated for release in the colon.

16. The pharmaceutical composition of claim 15 wherein:

(a) the first component comprises a 5-ASA compound;

(b) the second component comprises a 5-ASA compound and a 4-APAA compound formulated for release in a distal portion of the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

17. The pharmaceutical composition of claim 15 wherein:

(a) the first component comprises a 5-ASA compound;

(b) the second component comprises:

(i) a 5-ASA compound formulated for release in the small intestine;

(ii) a 5-ASA compound and a 4-APAA compound formulated for release in a distal portion of the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

18. The pharmaceutical composition of claim 15 wherein:

(a) the first component comprises a 5-ASA compound;

(b) the second component is not present;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

19. The pharmaceutical composition of claim 15 wherein:

(a) the first component comprises a 5-ASA compound;

(b) the second component comprises a 5-ASA compound formulated for release in the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

20. The pharmaceutical composition of claim 15 wherein:

(a) the first component comprises a 4-APAA compound;

(b) the second component comprises a 5-ASA compound and a 4-APAA compound formulated for release in a distal portion of the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

21. The pharmaceutical composition of claim 15 wherein:

(a) the first component comprises a 4-APAA compound;

(b) the second component comprises:

(i) a 4-APAA compound formulated for release in the small intestine; and

(ii) a 5-ASA compound and 4-APAA compound formulated for release in a distal portion of the small intestine; (c) the third component comprises a 5-ASA compound and a

4-APAA compound.

22. The pharmaceutical composition of claim 15 wherein:

(a) the first component comprises a 4-APAA compound;

(b) the second component is not present;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

23. The pharmaceutical composition of claim 15 wherein:

(a) the first component comprises a 4-APAA compound;

(b) the second component comprises a 4-APAA compound formulated for release in the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

24. The pharmaceutical composition of claim 15 wherein:

(a) the first component is not present;

(b) the second component comprises a 5-ASA compound and 4-APAA compound formulated for release in a distal portion of the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

25. The pharmaceutical composition of claim 15 wherein:

(a) the first component is not present;

(b) the second component comprises:

(i) a 5-ASA compound formulated for release in the small intestine;

(ii) a 5-ASA compound and 4-APAA compound formulated for release in a distal portion of the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

26. The pharmaceutical composition of claim 15 wherein:

(a) the first component is not present;

(b) the second component comprises a 5-ASA compound formulated for release in the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

27. The pharmaceutical composition of claim 15 wherein:

(a) the first component is not present;

(b) the second component comprises a 5-ASA compound and 4-APAA compound formulated for release in a distal portion of the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

28. The pharmaceutical composition of claim 15 wherein:

(a) the first component is not present;

(b) the second component comprises:

(i) a 4-APAA compound formulated for release in the small intestine; and

(ii) a 5-ASA compound and 4-APAA compound formulated for release in a distal portion of the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

29. The pharmaceutical composition of claim 15 wherein:

(a) the first component is not present;

(b) the second component comprises a 4-APAA compound formulated for release in the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

30. A method of treating an inflammatory gastrointestinal condition comprising administering to a subject in need thereof a pharmaceutical composition of any of 1-29.

31. Use of a pharmaceutical composition of any of claims 1-29 in the manufacture of a medicament for treatment of an inflammatory gastrointestinal condition.

* * * * *

THE CLAIMS

We claim:

1. A pharmaceutical composition comprising two or more therapeutic agents selected from the group consisting of:
 - (a) azo-bonded 4-APAA compound;
 - (b) non-azo bonded 4-APAA compound;
 - (c) azo-bonded 5-ASA compound;
 - (d) non-azo bonded 5-ASA compound;
 - (e) 4-APAA compound azo bonded to a 5-ASA compound.
2. The pharmaceutical composition of claim 1 further comprising a third therapeutic agent selected from the group consisting of: steroids, antibiotics,
3. The pharmaceutical composition of claim 1 formulated to deliver the therapeutic agents to the small intestine and/or the colon.
4. The pharmaceutical composition of claim 1 formulated to release the therapeutic agents along the length of the small intestine and the colon.
5. The pharmaceutical composition of claim 1 formulated to release the therapeutic agents along the length of the distal portion of the small intestine and the colon.
6. The pharmaceutical composition of claim 1 formulated to release the therapeutic agents along the length of the colon.
7. The pharmaceutical composition of claim 1 formulated to pass through the stomach and to release the active agent in the intestine.
8. The pharmaceutical composition of claim 1 formulated as a suppository.
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14. The pharmaceutical composition of claim 1 formulated for administration to the eye.
15. The pharmaceutical composition of claim 1 formulated to release:
 - (a) at least one component selected from:
 - (i) a first component comprising one or more of the therapeutic agents formulated for release in the stomach,
 - (ii) a second component comprising one or more of the therapeutic agents formulated for release in the small intestine or distal portion of the small intestine, and
 - (b) a third component comprising one or more of the therapeutic agents formulated for release in the colon.
16. The pharmaceutical composition of claim 15 wherein:
 - (a) the first component comprises a 5-ASA compound;
 - (b) the second component comprises a 5-ASA compound and a 4-APAA compound formulated for release in a distal portion of the small intestine;
 - (c) the third component comprises a 5-ASA compound and a 4-APAA compound.
17. The pharmaceutical composition of claim 15 wherein:
 - (a) the first component comprises a 5-ASA compound;
 - (b) the second component comprises:
 - (i) a 5-ASA compound formulated for release in the small intestine;
 - (ii) a 5-ASA compound and a 4-APAA compound formulated for release in a distal portion of the small intestine;
 - (c) the third component comprises a 5-ASA compound and a 4-APAA compound.
18. The pharmaceutical composition of claim 15 wherein:
 - (a) the first component comprises a 5-ASA compound;

- (b) the second component is not present;
 - (c) the third component comprises a 5-ASA compound and a 4-APAA compound.
19. The pharmaceutical composition of claim 15 wherein:
- (a) the first component comprises a 5-ASA compound;
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 - (c) the third component comprises a 5-ASA compound and a 4-APAA compound.
20. The pharmaceutical composition of claim 15 wherein:
- (a) the first component comprises a 4-APAA compound;
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 - (c) the third component comprises a 5-ASA compound and a 4-APAA compound.
21. The pharmaceutical composition of claim 15 wherein:
- (a) the first component comprises a 4-APAA compound;
 - (b) the second component comprises:
 - (i) a 4-APAA compound formulated for release in the small intestine; and
 - (ii) a 5-ASA compound and 4-APAA compound formulated for release in a distal portion of the small intestine;
 - (c) the third component comprises a 5-ASA compound and a 4-APAA compound.
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24. The pharmaceutical composition of claim 15 wherein:

- (a) the first component is not present;
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31. Use of a pharmaceutical composition of any of claims 1-29 in the manufacture of a medicament for treatment of an inflammatory gastrointestinal condition.